PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P03-118	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP 03/15943	International filing date *(day/month/year)* 12.12.2003	Priority date *(day/month/year)* 13.12.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant OTSUKA PHARMACEUTICAL CO., LTD. et Al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03.05.2004	04.03.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel: +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Zeinstra, H Telephone No. +31 70 340-2824

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP 03/15943

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-38 as originally filed

Claims, Numbers

1-11 as originally filed

Drawings, Sheets

1/22-22/22 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 2-7,10,11

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 2-7,10,11 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1,8,9
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1,8,9
Industrial applicability (IA)	Yes:	Claims	1,8,9
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1 Claims 1, 2, 5 and 10 have been drafted as separate independent claims. However claims 2, 5 and 10 seem to relate effectively to the same subject-matter of claim 1 and to differ from that claim only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack at least conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it impossible to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims 2, 5 and 10 do not meet the requirements of clarity to such an extend that, no extensive examination can be performed on behalf of said claims and their dependent claims (see Article 34.4(b) PCT)

2 It would have been appropriate to amend the claims defining the relevant subject-matter using only one independent claim followed by dependent claims covering features which are merely optional (Rule 6.4 PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3 Reference is made to the following documents:
D1: US-A-5 785 049 (BURR JOHN D ET AL) 28 July 1998 (1998-07-28)
D2: US-A-5 435 297 (KLEIN CHRISTOPH) 25 July 1995 (1995-07-25)

4 Present claim 1 is unclear. The feature "...wherein the inhalation device for transpulmonary administration...by the inhalation-induced pressure" mainly refers to the use of the device without clearly defining the technical feature which allows this particular use. Therefore the feature cannot distinguish claim 1 from the prior art.

4.1 Insofar as the claim can be understood, it appears that its subject matter is not inventive over document D1 in view of document D2. In particular, document D1 which is considered to represent the most relevant state of the art, discloses (cf. column 7, line 66 - column 10, line 65; figures 1,2)
An inhalation device for transpulmonary administration comprising:
a chamber (12) for containing a pharmaceutical composition which is pulverized into fine particles by an air-generated impact for dispersal in air;
an air inlet flow path (44) for introducing to the chamber (12) outside air to apply the air-generated impact to the pharmaceutical composition and for injecting the outside air toward the pharmaceutical composition;
an inhalation flow path (46) having a suction port (16) located inside the chamber (12) to inhale the pulverized pharmaceutical composition;
a housing (11) for accommodating the chamber (12), the air inlet flow path (44), and the inhalation flow path (46);
a mouthpiece (30,32) provided at one end of the housing (11), the mouthpiece (30,32) being provided with a mouth-side flow path (30) which communicates with the inhalation flow path (46), and an auxiliary flow path (54) for directly inhaling the outside air which does not communicate with the inhalation flow path (46);
wherein the inhalation device for transpulmonary administration is configured such that the air-generated impact is applied to the pharmaceutical composition by the outside air which flows into the chamber (12) by inhalation induced pressure generated when a user (patient) inhales air, and the pulverized pharmaceutical composition is introduced to the mouth-side flow path (30), and at the same time the outside air is directly introduced to the auxiliary flow path (54) by the inhalation-induced pressure.

4.2 the subject matter of claim 1 differs in that:
the auxiliary flow path (54) for directly inhaling the outside air does communicate with the mouth-side flow path (30).

4.3 In view of said difference, the subject matter of claim 1 is new and meets the requirements of Article 33(2) PCT

4.4 The problem to be solved by the present invention may therefore be regarded as preventing the coalescence / agglomeration of fine particles (see the description at page 19, lines 2 - 11).

4.5 The solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33.3 PCT) for the following reasons:

4.6 The feature that "the auxiliary flow path does not communicate" is described in document D2 (cf column 3, line 30 - column 4, line 44, figure 4) as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal design option to include this feature in the device described in document D1 in order to solve the problem posed.

5 Dependent claims 8 and 9 do not appear to contain any additional features, which in combination with the features of any claim to which they refer, give rise to subject-matter that involves an inventive step (Article 33(3) PCT) as all the features introduced with these claims seem to be known while used with a known corresponding effect.

5.1 In particular:
- the features of claim 8 are disclosed in combination with the features of claim 1 in D1 (cf page 1, left-hand column, line 10 - right-hand column, line 5; figure 1).
- the feature "check valve" of claim 9 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.
- Therefore the subject matter of claims 8 and 9 does not involve an inventive step

6 The device described in the claims is industrially manufacturable, and therefore the requirements of Article 33(4) PCT are met.